



8EHQ-0396-13597

ORIGINAL

## NORTH AMERICAN SHARED SERVICES

SCHMIDT 3/28/96

CN 5255  
PRINCETON, NJ 08543-5255

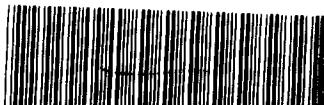
TEL: (609) 452-5000



February 28, 1996

8EHQ-96-13597  
INIT 03/05/96MAIL # P 257 618 825  
RECEIPT REQUESTED

OPPT Document Processing Center (7407)  
Room E-G99  
Attn: Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics (OPPT)  
US Environmental Protection Agency  
401 "M" Street, S.W.  
Washington, DC 20460



88960000077

RE: TSCA §8(e) Notification of Substantial Risk

RECEIVED  
OPPT/MIC  
3/28/96

Dear Sir or Madam:

Rhône-Poulenc Inc. is providing this notice to the Agency in accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA). We are submitting interim data for p-nonylphenol (CAS # 104-40-5) obtained from a preliminary uterine weight assay in Sprague-Dawley rats. This study was sponsored by the CMA Alkylphenol/Alkylnaphthalene Ethoxylates Panel. While we do not believe the results of this assay represent a substantial risk to human health or the environment, we are nevertheless reporting them to the EPA.

The following describes the results of a uterine weight screening assay conducted in Sprague-Dawley rats. The test material, p-nonylphenol, was administered by gavage to ovariectomized rats at doses of 0, 30, 100 and 300 mg/kg for 3 days. After the dosing period, rats were sacrificed and uterine weights measured. Mean uterine weights were 1.175, 0.165, 0.178 and 0.285 g, respectively, for the control, low, mid and high dose groups. Uterine weight variations within groups were ±15-30%.

Interpretation of these findings is difficult due to the large inter-animal variability. Data interpretation is further complicated by the apparent lack of an appropriate response in the positive control groups, raising a question of the assay's validity. In addition, toxicity was present in the high dose animals and consisted of weight loss, diarrhea, soiled ano-genital area, loose stools, lethargy, few feces and chromorhinorrhea.

Based on the toxicity seen at the high doses and the amount of variation among individual animals within groups, the effect is not believed to represent substantial risk. The CMA

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Alkylphenol/Alkylphenol Ethoxylates Panel is currently evaluating what, if any, additional studies may be done.

Rhone-Poulenc Inc. hereby asserts that none of the information contained herein is confidential business information (CBI). Should you have any questions, or require any further information, please call (609) 452-5082.

Very truly yours,

RHONE-POULENC, INC.



James E. Blum  
Manager, Product Safety

JEB: 96-021L.DOC

## Triage of 8(e) Submissions

Date sent to triage: 7/17/96

NON-CAP

CAP

Submission number: 13597A

TSCA Inventory:

Y    N    D

Study type (circle appropriate):

Group 1 - Gordon Cash (1 copy total)

ECO                  AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX                SBTOX            SEN                w/NEUR

Group 3 -HERD (1 copy each)

STOX	CTOX	EPI	<input checked="" type="radio"/> RTOX	GTOX
STOX/ONCO	CTOX/ONCO	IMMUNO	<input checked="" type="radio"/> CYTO	NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

- This is the original 8(e) submission; refile after triage evaluation.
- This original submission has been split; rejoin after triage evaluation.
- Other:

### Photocopies Needed for Triage Evaluation

entire document:  1    2    3

front section and CECATS:  1    2    3

Initials: JW

Date: 6/26/96

## CICA TRIAGE TRACKING DBASE ENTRY FORM

CICA'S DATA:  
Submission # 8EHQ-0396-13597  
SIE: A

TYPE: IND SUPP FL WP

SUBMITTER NAME: Rhone - PoulenC  
Inc.

DISPOSITION:

0639 REFER TO CHEMICAL SCREENING

0678 CAP NOTICE

SUB. DATE: 02/28/96 OTS DATE: 03/05/96 CSRAD DATE: 03/28/96

CHEMICAL NAME:

CAS#

104-40-5

## INFORMATION REQUESTED: FL WP DATE:

## VOLUNTARY ACTIONS:

- 0401 NO ACTION REPORTED
- 0402 STUDIES PLANNED/UNDERWAY
- 0403 NOTIFICATION OF WORKER/OTHERS
- 0404 LABEL/MSDS CHANGES
- 0405 PROCESS/HANDLING CHANGES
- 0406 APP/USE DISCONTINUED
- 0407 PRODUCTION DISCONTINUED
- 0408 CONFIDENTIAL

## INFORMATION TYPE: P F C INFORMATION TYPE: P F C INFORMATION TYPE: P F C

- |                               |          |                                |          |                        |          |
|-------------------------------|----------|--------------------------------|----------|------------------------|----------|
| 0201 ONCO (HUMAN)             | 01 02 04 | 0216 EP/CLIN                   | 01 02 04 | 0241 IMMUNO (ANIMAL)   | 01 02 04 |
| 0202 ONCO (ANIMAL)            | 01 02 04 | 0217 HUMAN EXPOS (PROD CONTAM) | 01 02 04 | 0242 IMMUNO (HUMAN)    | 01 02 04 |
| 0203 CELL TRANS (IN VITRO)    | 01 02 04 | 0218 HUMAN EXPOS (ACCIDENTAL)  | 01 02 04 | 0243 CHEM/PHYS PROP    | 01 02 04 |
| 0204 MUTA (IN VITRO)          | 01 02 04 | 0219 HUMAN EXPOS (MONITORING)  | 01 02 04 | 0244 CLASTO (IN VITRC) | 01 02 04 |
| 0205 MUTA (IN VIVO)           | 01 02 04 | 0220 ECO/AQUA TOX              | 01 02 04 | 0245 CLASTO (ANIMAL)   | 01 02 04 |
| 0206 REPRO/TERATO (HUMAN)     | 01 02 04 | 0221 ENV. OCC/C REL/FATE       | 01 02 04 | 0246 CLASTO (HUMAN)    | 01 02 04 |
| 0207 REPRO/TERATO (ANIMAL)    | 01 02 04 | 0222 EMER INCI OF ENV CONTAM   | 01 02 04 | 0247 DNA DAM/REPAIR    | 01 02 04 |
| 0208 NEURO (HUMAN)            | 01 02 04 | 0223 RESPONSE REQUEST DELAY    | 01 02 04 | 0248 PROD/USE/PROC     | 01 02 04 |
| 0209 NEURO (ANIMAL)           | 01 02 04 | 0224 PROD/COMP/CHEM ID         | 01 02 04 | 0251 MSDS              | 01 02 04 |
| 0210 ACUTE TOX. (HUMAN)       | 01 02 04 | 0225 REPORTING RATIONALE       | 01 02 04 | 0299 OTHER             | 01 02 04 |
| 0211 CHIR. TOX. (HUMAN)       | 01 02 04 | 0226 CONFIDENTIAL              | 01 02 04 |                        |          |
| 0212 ACUTE TOX. (ANIMAL)      | 01 02 04 | 0227 ALLERG (HUMAN)            | 01 02 04 |                        |          |
| 0213 SUB ACUTE TOX (ANIMAL)   | 01 02 04 | 0228 ALLERG (ANIMAL)           | 01 02 04 |                        |          |
| 0214 SUB CHRONIC TOX (ANIMAL) | 01 02 04 | 0239 METAB/PHARMACO (ANIMAL)   | 01 02 04 |                        |          |
| 0215 CHRONIC TOX (ANIMAL)     | 01 02 04 | 0240 METAB/PHARMACO (HUMAN)    | 01 02 04 |                        |          |

## TRIAGE DATA: NON-CBI INVENTORY ONGOING REVIEW SPECIES TOXICOLOGICAL CONCERN: USE: PRODUCTION:

YES (CONTINUE)

NO (DROP)

MED

HIGH

DETERMINE:  
REFER:

NO (CONTINUE)

YES (DROP)

LOW

MED

HIGH

## COMMENTS:

Summary only  
Preliminary Uterine weight assay  
4 groups of undetermined #: 0, 30, 100, 300 mg/kg/day  
via gavage to ovariectomized rats for 3 days.  
General toxicity at high dose groups

Inconclusive because:

↓ uterine weights at all dose groups but ~~not~~ inverse dose-response.  
+ control group did not show an effect